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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/810,116	03/26/2004	Walter H. Olson	P-2988.14	8025
27581	7590	03/15/2006	EXAMINER	
MEDTRONIC, INC. 710 MEDTRONIC PARK MINNEAPOLIS, MN 55432-9924			EVANISKO, GEORGE ROBERT	
			ART UNIT	PAPER NUMBER
			3762	

DATE MAILED: 03/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/810,116

Applicant(s)

OLSON ET AL.

Examiner

George R. Evanisko

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 January 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-6, 8, and 15-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mehra (5243980) in view of Gilli et al (5191884).

Mehra teaches the sensing of atrial and ventricular events to define a cardiac grammar (columns 10 and 11), incorporates by reference several patents to define how detection of the different arrhythmias may function, and shows the priority-rule based logic set with a plurality of rules for delivery and withholding of therapy in figure 5e. In addition, Mehra teaches a plurality of anti-tachycardia pacing therapies and increasing defibrillation shocks after redetection/reconfirmation (columns 12-14) and teaches the use of nerve or drug stimulation (columns 2 and 17). But Mehra does not disclose continuing to fire the rule until the rule is not

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satisfied by a predetermined sequence of R-R intervals. Gilli teaches that it is known to continue to fire the rule to deliver therapy unless the rule is not satisfied by a predetermined sequence of R-R intervals by using a confirmation process to prevent unnecessary shocks when an arrhythmia has been detected but the heart reconverts before the therapy is applied to prevent pain to the patient from an unnecessary shock. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the heart therapy system as taught by Mehra, with the continuing to fire the rule until the rule is not satisfied by a predetermined sequence of R-R intervals as taught by Gilli, since such a modification would provide a heart therapy system and method with a step/element to continue to fire the rule to deliver therapy unless the rule is not satisfied by a predetermined sequence of R-R intervals by using a confirmation process to prevent unnecessary shocks when an arrhythmia has been detected but the heart reconverts before the therapy is applied to prevent pain to the patient from the unnecessary shock.

Claims 10-14 are rejected under 35 U.S.C. 103(a) as obvious over Mehra in view of Gilli.

The modified Mehra teaches the use of a microprocessor being controlled by RAM and DMA and a physician programming the device to deliver the particular therapies based on the particular arrhythmia (columns 11 and 12) and therefore provides a computer readable media with instructions to perform the method.

In the alternative, the modified Mehra discloses the claimed invention except for the computer readable media containing instructions to perform the method. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the

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ICD system and method with microprocessor and memory as taught by the modified Mehra, with the computer readable media containing instructions to perform the method since it was known in the art that ICD systems and methods use a computer readable media containing instructions to perform the method to allow the system to function automatically and/or to allow the physician to be able to program the device to fit the particular patient.

Claims 7 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over the modified Mehra.

The modified Mehra discloses the claimed invention except for the plurality of cardioversion therapies with different amounts (claim 7) and reconfirming the arrhythmia to deliver an increased cardioversion therapy (claim 9). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the ICD method as taught by the modified Mehra, with the plurality of cardioversion therapies with different amounts and reconfirming the arrhythmia to deliver an increased cardioversion therapy since it was known in the art that ICD methods use the plurality of cardioversion therapies with different amounts and reconfirming the arrhythmia to deliver an increased cardioversion therapy to allow a higher level of cardioversion therapy to be delivered to the patient to quickly revert the arrhythmia if the first cardioversion therapy is not successful and the arrhythmia is still present.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

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A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-19 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 5-17, 1-13, 1-10, 1-7, and 1 of U.S. Patent Nos. 6731978, 6487443, 6259947, 5991656, and 5545186, respectively. Although the conflicting claims are not identical, they are not patentably distinct from each other because the patented claims are more narrow and meet the limitations of the broader applications claims. In addition, it would have been obvious to one having ordinary skill in the art at the time the invention was made to incorporate into the patented claims the continuing to fire the rule until the rule is not satisfied by a predetermined sequence of R-R intervals, different therapies and reconfirmations prior to delivering a higher therapy and a computer readable media containing instructions to perform the method, since it was known in the art that ICD methods and systems use: a step or element to continue to fire the rule until the rule is not satisfied by a predetermined sequence of R-R intervals by using a confirmation process to prevent unnecessary shocks when an arrhythmia has been detected but the heart reconverts before the therapy is applied to prevent pain to the patient from the unnecessary shock; different therapies, such as ATP, cardioversion, drugs, and defibrillation to revert the arrhythmias; a reconfirmation prior to delivery of a higher energy pulse, to make sure the arrhythmia is still occurring and to increase the energy over the prior pulse which was not effective; and a computer readable media containing instructions to

perform the method to allow the system to function automatically and/or to allow the physician to be able to program the device to fit the particular patient.

Response to Arguments

Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection necessitated by amendment. It is noted that the system of the present application checks the R-R interval after the initial firing of the rule to determine if the therapy for the rule should be applied and therefore is the same as any of the other numerous prior art references that show a confirmation/reconfirmation of the arrhythmia prior to shock to prevent unnecessary shocks from being delivered to the patient. In addition, it is noted that the previous detailed action used common knowledge or well-known in the art statements in the 103 rejections and that these statements are taken to be admitted prior art because applicant failed to traverse the examiner's assertion of common knowledge or well-known in the art.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to George R. Evanisko whose telephone number is 571 272 4945.

The examiner can normally be reached on M-F 6:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 571 272 4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


George R Evanisko
Primary Examiner
Art Unit 3762

3/13/06

GRE
March 13, 2006